UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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| In re: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION | MDL No. 15-2666 (JNE/FLN) |
| This Document Relates To: *All Cases* | |

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF MICHAEL KEEN**

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## Rules

Fundamentally, the claims plaintiffs have asserted in this MDL boil down to two questions that could potentially relate to the opinions offered by Michael Keen (1) do particles correlate with bacterial load, also known as bioburden, in the air; and (2) does the Bair Hugger system increase the number of particles in the operating room and over the surgical site during an operation?

The second question is uncontroverted: 3M admits that every single study done to date, both peer-reviewed studies and internal company testing, demonstrate an increase in particles over the surgical site when the Bair Hugger system is on and set to warm. *See* Ex. B, Deposition of 3M 30(b)(6) Designee Al Van Duren at 258:5-13. This key admission was not provided to Michael Keen or the vast majority of the other experts Defendants hope to call in this case.

One question to be considered by the jury in this case is whether particles correlate with bacteria. Experts proffered by both Plaintiffs and Defendants agree that particle counts are a reliable method of approximating the bioburden in the air. The International Consensus answers the first question an unequivocal yes as well: a "strong consensus" of 93% of the Delegates agree that "bacteria can be considered as part of the total mass of particulates in the air," and note studies have concluded "airborne particulate count should be considered as a potential surrogate for airborne microbial density."

3M expert Michael Keen disclosed opinions on a host of subjects that relate, directly or indirectly, to the questions identified above. With a few narrow exceptions, Keen lacks the qualifications to offer expert testimony on those topics.

Keen works in a hospital in Canada. *See* Michael Keen, "Expert Report of Michael Keen," (Keen Report) attached here as Ex. A at 1. But he is not a doctor or part of a medical team that works in the OR. *Id.* at 2. He is not a researcher – his CV does not list a single publication. Ex. C, Exhibit 2 to the Deposition of Michael Keen. He did not conduct any experiments or testing or simulations or calculations in connection with this case. Ex. D, Deposition of Michael Keen ("Keen Dep.") 44:17-45:24. Keen does not design HVAC systems for operating rooms. Keen Dep. 146:9-12. Keen does not design products and never has. Keen Dep. 201:13-23.

It would appear that the sole basis for Keen's far-ranging testimony is his membership in committees of American Society of Heating, Refrigeration and Air-Conditioning Engineers (ASHRAE). But there is no indication that his committee membership experience gave Keen anything approaching the level of expertise necessary to support the proffered opinions.

Keen's proposed testimony jumps from operating room design to areas as far-reaching as the potential for thermal plumes to protect patients from settling bacteria. He offers opinions on particle and bacteria movement, surgical site infections, application of filtration standards to medical devices, ability of particles to carry bacteria, and even air flow characteristics during Bair Hugger operation. *See* Keen Rpt.

Most of the opinions offered by Mr. Keen are outside of his area of experience and should be excluded from evidence pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Federal Rules of Evidence 702 and 703.

At a high level, Mr. Keen should be precluded from opining in any way on the following topics:

- The safety and efficacy of the Bair Hugger and its filtration system in an operating room, including the air flow generated by a Bair Hugger in operation;
- Filtration requirements for medical devices, including specifically whether the Bair Hugger's intake filter was "an appropriate filter to include in the unit." Keen Rpt. at 23.
- Surgical site infections including the potential sources and/or transmission pathways for such infections, including the potential for Bair Hugger to contribute to such infections;
- Operating room airflow characteristics including the potential disruption of OR airflow caused by staff and other heat- and/or turbulence producing elements and the positive or negative impacts of thermal plumes;
- Movement of particles and bacteria in OR air flows, including the efficacy or validity of techniques used to study such particle movement;
- Migration of bacteria from contaminated Bair Hugger devices into the OR.

## I. LEGAL STANDARDS

Under Federal Rule of Evidence 702, expert testimony is admissible if a witness is "qualified…by knowledge, skill, experience, training, or education," and if his or her testimony is 1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; 2) "based upon sufficient facts or data"; and 3) "the product of reliable

principles and methods" that 4) have been reliably applied "to the facts of the case." Fed R. Evid. 702. Under the Supreme Court's two-part test to govern the admissibility of expert testimony under Rule 702, evidence should be admitted only if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597.

Expert testimony is reliable only if the expert is qualified to give an opinion and his methodology is scientifically valid and is properly applied to the facts in issue. *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1146 (D. Minn. 2011). Qualifications of a witness are necessarily contextual, such that an expert who is qualified in one field may not necessarily be an expert in a different field. *See Wheeling Pitts. Steel v. Beelman River Terminals*, 254 F.3d 706, 716 (8th Cir. 2001) (reversing district court's admission of testimony where expert was qualified in one subject matter but not qualified by "knowledge, skill, experience, training, or education" in another subject area).

*Daubert* set forth several factors for courts to use when determining a proffered expert's reliability. *Id*. These factors are: (1) "whether it can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "[the method's] 'general acceptance.'" *Presley v. Lakewood Eng'g & Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (*citing Daubert*, 509 U.S. at 593-94); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). These factors are not "exhaustive or limiting, and a court must use the factors as it deems fit to tailor an examination of the reliability of expert testimony to the facts of each case." *Presley*, 553 F.3d at 643 (*citing Shuck v. CNH America, LLC*, 498 F.3d 868, 874 (8th Cir. 2007)).

The district court may consider "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 449 (8th Cir. 2007) (*quoting Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686-87 (8th Cir. 2001)). The district court must be a gatekeeper who "separates expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

While Rule 703 allows an expert to rely on otherwise inadmissible data or information, Rule 703 does not allow an expert in one field to merely parrot the opinions of an expert in a different field. *See Dura Automotive Systems of Indiana, Inc., v CTS Corp.*, 285 F.3d 609 (7th Cir. 2002).

## II. ARGUMENT

### A. Mr. Keen Is Not Qualified To Give Expert Testimony As To The Selection, Design, or Efficacy Of The Bair Hugger Intake Filter

Mr. Keen lacks the qualifications to offer an opinion on the appropriateness of the intake filter on 3M's Bair Hugger. To offer testimony under Rule 702, a witness must qualify as an expert in a field based on his or her "knowledge, skill, experience, training, or education." Keen proposes to testify that the filtration standard for an operating room HVAC system should be applied to a medical device.

Keen is not qualified as an expert on medical device design, much less the selection of a filter or design of a filtration system for a medical device. Mr. Keen's

report does not cite any studies, standards, or authorities for designing or evaluating filtration requirements for medical devices. He merely grafted a standard that applies to operating room design and construction (ASHRAE 52.2) onto a medical device. In deposition, Keen admitted that the ASHRAE standards do not apply to medical devices. Keen Dep. at 322:23-25. Another 3M expert, Kuehn, testified unequivocally that ASHRAE 52.2 does not apply to medical devices. Ex. E, Deposition of Thomas Kuehn ("Kuehn Dep.") 256:1-13.

Keen admitted he has no experience in designing a medical device. Keen Dep. at 61:12-15, 323:1-4. He admitted he has no knowledge of filtration standards for medical devices. *Id*. at 324:2-6. Keen has never designed a filter for a medical device. *Id.*

Given Keen's lack of knowledge, skill, experience, training, or education in designing medical devices or filtration systems for medical devices, he is not "qualified as an expert" within the meaning of Rule 702 to offer any testimony related to the Bair Hugger or its use in an operating room. This Court should exclude any testimony from Mr. Keen as to the safety and efficacy of the Bair Hugger unit or its filter and in particular, his opinion that the Bair Hugger's intake filter was "an appropriate filter to include on the unit." Keen Rpt. at 23.

### B. Keen Is Not Qualified to Give Expert Testimony As To Operating Room Design or Airflow Characteristics

Keen seeks to offer testimony about air flow and thermal loads in operating rooms and the potential benefits of thermal plumes. Keen is not qualified to offer such testimony. Nothing in his CV demonstrates a level of training, skill, or experience to

testify about operating room airflows generally, much less the potential impact of Bair Hugger or other heat-generating sources on operating room airflows.

The bulk of his experience with his hospital has been in an advisory and administrative, not a design, capacity. *See* Ex. C, Keen CV. Mr. Keen has not disclosed any special training or education on the design of an operating room HVAC system in his Curriculum Vitae or Expert Report. When questioned on his background in engineering and operating room design at his deposition, Mr. Keen testified that he had never designed an HVAC system for an operating room on his own and would not be comfortable designing one on his own. Keen Dep. 145:15-17; 146:9-12; 294:10-13. Further, he has only participated in the design of one United States operating room, and that was more than twenty years ago. Keen Dep. at 148:24-25; 294:23-295:2.

Similarly, Keen is not qualified to testify about the theory that a thermal plume could operate as a protective barrier. Keen's CV does not indicate any research or experimental work in that field before this litigation, and he has not disclosed any such research or experimental work during this litigation. Keen testified that he never calculated the buoyancy or the force of a thermal plume. Keen Dep. 307:21-308:1. As described in more detail below, Keen does not hold himself out as an expert in operating room air flow and has never personally performed particle measurement. *Id*. at 282:18-283:12; 268:1-12.

In short, Keen merely regurgitates opinions offered by a single researcher in a separate discipline. Keen Dep. 309:2-7. Rule 703 does not allow an expert in one field to merely parrot the opinions of a different expert, especially where the creation of the data

required the use of professional discretion in a disparate discipline. *See Dura Automotive*, 285 F.3d at 613. Because Mr. Keen does not meet the Rule 702 requirements to be qualified as an expert on these subjects, they should be excluded from his testimony.

### C. Keen Is Not Qualified To Testify About Particle Flow Studies

Keen criticizes the accuracy of particle tracking studies using neutrally-buoyant bubbles. This testimony should be excluded because Keen is not qualified as an expert in this subject matter. Keen has never personally conducted experiments or tests of particle sampling. Keen Dep. 282:18-283:3. Prior to his work on this case, Keen had never considered the use of neutrally buoyant bubbles in tracing or simulating particle flow. *Id.* at 285:5-9. Mr. Keen was unable to give any specific comparisons of the densities of bubbles as opposed to particles in the air. *Id. at* 282:5-13. Keen testified he would defer to particle physics experts on issues related to particle physics, including principles of how particles settle over time. *Id.* at 293:8-12, 295:6-13. Mr. Keen has never done any particle measuring and has never used or been trained to use any of the tools that are used to measure particles in the air. *Id.* at 283:1-3; 283:4-12. Due to his lack of training and experience, Mr. Keen admitted that he is not able to offer any testimony on the accuracy of such particle measuring equipment. *Id.* at 283:13-19.

Mr. Keen has not disclosed any knowledge, skill, experience, training, or education that would qualify him to criticize the use of neutrally-buoyant bubbles in particle flow analysis as described in peer-reviewed journals. As such, his testimony on those topics is not admissible under Rule 702 and should be excluded.

### D. Keen Is Not Qualified to Testify About the Risk of Infection During Surgery

A central issue in this litigation is whether the Bair Hugger units increase the risk of particles causing surgical site infections. Based on his lack of knowledge, skill, experience, training, or education, Mr. Keen is fundamentally unsuited to opine on that issue.

Mr. Keen, by his own admission, is not a microbiologist and has no training as a microbiologist or aerobiologist. *Id.* at 165:5-10. He admitted that he would rely on a microbiologist to quantify the risk to patients from pathogens or particles that carry pathogens, and that he would defer to a particle physics specialist regarding how particles settle over time. *Id.* at 179:19-24; 288:10-12; 295:6-296:2.

Mr. Keen is not an epidemiologist, and testified he would defer to an epidemiologist or microbiologist on the number of particles or pathogens it would take to cause a surgical site infection and would not be offering testimony regarding how many particles or pathogens would be required. *Id.* at 299:24-300:8; 300:11-19. Further, he admitted that he would defer to an infectious disease specialist or microbiologist regarding the ability of a particle to carry a microorganism. *Id.* at 287:25-288:5; 290:24-291:5. Mr. Keen has never done any particle counting, and he has never been trained to do any particle counting. *Id.* at 315:22-316:10.

Given Mr. Keen's testimony that he lacks experienced and would have to defer to epidemiologists, microbiologists, and particle physics specialists regarding issues related to particles, pathogens, and other contaminants moving through the surgical area and

their relation to the Bair Hugger and surgical site infections, none of his testimony in those areas is admissible. Therefore, the court should exclude the portions of Mr. Keen's report that deal with the number of particles or pathogens present in or attributable to a Bair Hugger unit in the operating room and any effects they might have on increasing the risk of infection.

### E. Keen Is Not Qualified to Testify About The Ability of Particles to Carry Bacteria

Keen proposes to offer testimony about the ability of particles to carry bacteria. But Keen is not qualified to offer such opinions. Keen has no education, experience, training, or other source of knowledge that would support his opinions other than a single cited reference. Other than sitting on an ASHRAE committee, Keen identified no relevant experience in this area. The only source for his testimony was a published reference. When asked, Keen conceded that he would defer to microbiologists or infection disease physicians on those subjects. *Id.* at 288:21-291:5.

### F. Mr. Keen Should be Prohibited from Offering Any Testimony About Bair Hugger Operation of Air Flows

Mr. Keen has never evaluated a Bair Hugger in operation as it would be during surgery, yet he offers opinions on the operating of the device and its resulting air flows in his report. Because Mr. Keen has no valid basis for those opinions, they should be excluded.

Mr. Keen testified that he could not recall evaluating a Bair Hugger in operation in an operating room. *Id.* at 38:21-5. He testified that he had never seen or touched a Bair Hugger blanket. *Id.* at 256:22-24. To try to understand how Bair Hugger works in the

operating room, Mr. Keen testified that he relied, perhaps solely, on YouTube videos. *Id.* at 229:1-6.

Relying on YouTube videos of unknown origin to assist in preparing his expert report is not a reliable methodology, especially because Mr. Keen could not provide citations to or otherwise identify those videos. *Id. at* 117:17-118:6; 222:8-225:3; 227:2-229:6; 252:2-19. Mr. Keen's failure to provide accurate citation or other identifying information relating to the videos precludes the Plaintiffs from examining them or providing them to Plaintiffs' experts for evaluation and potential cross-examination of Mr. Keen.

As discussed above, Mr. Keen has had very limited exposure to Bair Hugger units. He testified in his deposition that he has never seen or touched a Bair Hugger blanket itself. *Id.* at 256:22-24. He testified that he has never knowingly observed a Bair Hugger being used in a surgery (Keen Dep. 38:21-5), therefore his only observations of a Bair Hugger being used would be from these uncited and unidentified videos.

Despite having done no testing, experiments, measurement, or even direct observation, Keen seeks to testify that the Bair Hugger is "draped, taped, and secured in a manner that directs air exiting the blanket away from the surgical site." Keen Rpt. 1. Keen offers no source for that opinion. He did not disclose any meetings with orthopedic surgeons, OR staff, or anyone else would could have provided him with a basis on which to ground his statement.

He later states "Air eventually escapes primarily through the head and neck area of the patient." Keen Rpt. 13. But Keen did not perform any measurements or tests to see

where air flows in and around the Bair Hugger. Instead, he learned it from a 3M video posted on YouTube. Keen Dep. 251:21-252:14. A self-serving 3M propaganda clip produced in response to this litigation is not a reliable source to determine movement of air or the absence thereof. In fact, 3M's expert who measured temperature of the air underneath the surgical table indicated that the assumption that al the air comes out of the head and neck area is incorrect. Ex. F, Deposition of Gary Settles at 94:23-96:12.

3M bears the burden of demonstrating that Mr. Keane's reliance on other data is "reasonable" before his testimony can be admitted. Federal Rule of Evidence 703. Here, where 3M's expert either cannot point to the source of the information upon which his opinions are based, or admits that his opinions were based solely on watching a video that 3M posted on the internet in response to proceedings in this litigation, 3M surely cannot meet that burden. The Court should exclude any testimony or opinions based on Keen's unreliable methods and lack of qualifications.

### G. Keen's Testimony on Bair Hugger Filter Tests Should Be Excluded

Keen's report contains bare-bones descriptions of tests that were allegedly performed on what he describes as "Bair Hugger Filters." Mr. Keen did not perform the tests himself. *See* Keen Rpt. at 8. The testing was performed in April of 2016, well after this litigation was initiated. *Id*. Keen offered no description of the conditions under which the testing occurred that would demonstrate that the testing was conducted in a reliable fashion. *Id*. He offers no basis on which to testify that the products tested were, in fact, filters for the Bair Hugger devices he claims them to be. *Id*.

All the information Keen received about these filter tests was provided by counsel for 3M. His report merely describes the content of an out of court test conducted by an unknown third party at the behest of 3M's litigation counsel. Keen has no direct experience, made no effort to validate the experimental protocol, the source of the filters, or even that they were representative of current *or* past Bair Hugger Filters. Given the complete absence of information by which the methodology used for testing could be deemed reliable, Keen's testimony regarding this testing should be excluded.

### H. Testimony Derived From Canadian Standards

Mr. Keene is employed by a Canadian hospital. Keen Report at 1-2. In his report, he cites in various places to standards that apply to hospitals in Canada. *See*, *e.g.*, Keen Report at 3 (citing Canada's HEPA filtration standard for specialized operating rooms). Given that none of the surgeries at issue in the present litigation occurred in Canadian hospitals, it is not appropriate to rely on Canadian standards without at least elucidating a basis for such reliance. Keen's report contains no such explanation. Keen should therefore be excluded from offering testimony as to any Canadian standards.

### I. Testimony Related to Experiments By Michael Buck

Mr. Keen did not review the report completed by Michael Buck, and as such should not be allowed to offer any testimony in opposition to Buck's experiments that showed particles coming out of a Bair Hugger. Keen Dep. at 284:9-13.

## III. CONCLUSION

For the reasons stated above, Plaintiffs ask the Court to Exclude the Deficient Portions of the Testimony of Michael Keen.

Dated: September 12, 2017

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